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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,781	01/11/2001	Elliott Farber	14358-308	1721

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,781

Applicant(s)

FARBER, ELLIOTT

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/11/01, 10/31/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 23-46 and 54-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed. + 51-53
- 6) ☒ Claim(s) 1-5, 16-22 and 47-50 is/are rejected.
- 7) ☒ Claim(s) ~~1-5, 16-22 and 47-50~~ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species of anionic or nonionic emulsifiers, in Paper No. 10 is acknowledged. Claims 1-5, 16-22 and 47-53 are drawn to the elected species and the search is accordingly directed to said claims.

The traversal is on the ground(s) that each of claims 1-81 recites an emulsifier or an emulsifier system that includes at least one anionic or nonionic emulsifier and that all other independent claims are examples of claim 1. This is not found persuasive because as set forth in paper No. 7, the claims are restricted to mutually exclusive species. Accordingly, the general test as to when claims are restricted is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second species. (see MPEP 806.4(f)). In the instant case, for example, the limitations set forth in species claimed in claims 40 is not included in claim 33 nor is it in claim 16 and likewise in other independent claims. The assertion that all claims are examples of claim 1 is not relevant.

Further, as clearly stated in the last paragraph of page 4 of the requirement, Paper No.7. Should Applicant believe that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species are obvious variants or clearly admit on the record that this is the case. Applicant has not set forth any evidence nor has he clearly admitted on the record that the recited species are obvious variants of each other. Accordingly, and for the reasons of record, the requirement is still deemed proper and is therefore made FINAL.

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2. Claims 6-15, 23-46, 54-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,281,236. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The patented claims 1, 8-9, 42 are directed to compositions comprising allantoin with at least an anionic emulsifier having a pH within the ranges of the instantly claimed pH. The patented claim differs in encompassing a narrower range of pH. However, it would have been obvious to one of ordinary skill in the art at the time of invention to

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practice the scope of instant claims by employing any anionic emulsifier taught in the patented claims and modify the pH by routine experimentation.

4. Claims 1-5, 16-22, 47-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,329,413. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope. The patented compositions only differ from the instant compositions in the amount of allantoin employed and their narrower range of pH. However, it would have been obvious to one of ordinary skill in the art at the time of invention to modify such quantities by routine experimentation to optimize the therapeutic effects of the compositions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, are rejected under 35 U.S.C. 102(b) as being anticipated by Mecca US Patent 3,954,989.

Mecca disclose allantoin containing compositions in combination with an acid, such as ascorbic acid or citric acid, and an anionic surfactant such as Veegum K, at pH of about 4-4.5 (see example 1, 4; col 3 line 43). Thus, Mecca's composition meets the limitations of the instant composition.

6. Claims 1-3, 16-17, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation).

The instant claims are directed to compositions comprising an allantoin, at least one anionic or nonionic surfactant, an acidic anionic polymer such as carboxypolymethylene, wherein the composition has a pH of about 3.0-6.0.

JP '013 discloses topical oil-in-water emulsions comprising allantoin, Carbopol 934 (carboxyvinyl polymer which is the same polymer as carboxypolymethylene) and optionally an anionic or non-ionic surfactant having a pH of about 5.5 (see claims 1, entire page 3-6, especially examples 1-2). Accordingly, JP '013 anticipates the limitations of the instant claims.

7. Claims 1-3, 16-17, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyder US Patent 4,806,262.

Snyder discloses emulsions comprising allantoin, Carbopol, a nonionic surfactant and cetyl alcohol having a pH of about 4.5-8.5. Accordingly, the compositions of Snyder meet all the limitations of the instant claims.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlen US Patent 4,707,354.

Garlen's discloses compositions containing allantoin, an non-ionic emulsifier, emollients such as cetyl alcohol, vegetable oil, and various sunscreen, preservatives and acceptable topical carriers at a pH of approximately 5 (see col 3-5). Accordingly, Garlent anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 1-5, 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '013 in view of Grollier et al US Patent 4,767,618 and Garlen US Patent 4,707,354.

The teachings of JP '013 are discussed above. JP 013 fails to teach the use of polygalactose or an emollient.

Grollier provides the conventional use of polygalactose and other equivalent thickening agents such as polyarabinan in topical delivery systems. Grollier discloses compositions comprising pure allantoin or allantoin in powdered flower, at least one anionic or nonionic surfactants, carboxypolymethylene, cetyl alcohol (emollient), and thickeners such as veegum or carraghenates (a polygalactose). (see abstract; col 4, lines 8-20; col 5, lines 4-25; col 6, lines 28-44; example 13, 19, 22-28; col 17-18).

Grollier does not explicitly teach the instant range of pH in his final formulations.

Garlen's teachings supplements Grolliers in that it provides dermatological creams containing allantoin, an non-ionic emulsifier, emollients such as cetyl alcohol, vegetable oil, and various sunscreen, preservatives and acceptable topical carriers (see col 3-5).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding conventional emollients such as cetyl alcohol or thickeners such as polygalactose, as suggested by Grollier, and improve the viscosity and physical characteristics of such emulsions. Accordingly, absence of showing criticality, the ordinary artisan would have been motivated to make such modifications, because as suggested by Grollier and Garlen, allantoin can be combined with other topically suitable ingredients into stable topical emulsions to provide their own intended therapeutic benefits.

10. Claims 1-4, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garlen US Patent 4,707, 354 in view of Goode et al US Patent 4,822,601 and France US Patent 4,767,618.

Garlen's teachings are discussed above. Garlen essentially teaches allantoin, an non-ionic emulsifier, emollients such as cetyl alcohol, vegetable oil, and various sunscreen, preservatives and acceptable topical carriers (see col 3-5). Garlen does not employ sodium stearyl lactylate or sodium isostearyl lactylate as an emulsifier system. However, Garlen acknowledges the use of any emulsifier system suitable in cosmetic art. (see col 2, lines 46-67).

Goode and France collectively teach the use of stearoyl lactylates as suitable emulsifiers in the cosmetic and topical pharmaceutical preparations. Goode teaches the therapeutic benefits of using of alkali metal salts of fatty acid lactylate esters in cosmetic base compositions including sodium stearoyl lactylate and sodium isostearoyl lactylate (see abstract; example 5, col 9-10, see table Series I-III, col 11, lines 51-67). France teaches that alkali lactylate fatty acid esters emulsifier systems provide a stable water in oil emulsion systems in cosmetic and pharmaceutical preparations. (see abstract; col 5, lines 23-67; col 6, lines 1-20; col 9, lines 9-33; col 10, lines 3-20). The compositions of Goode and France do not contain allantoin.

Nevertheless, since Garlen views suitable emulsifying systems to be equally effective in formulating an emulsion containing allantoin, absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the emulsifier system of Good in place of Garlen's, because as suggested by both Goode and France employing sodium stearoyl lactylate and sodium isostearoyl lactylate would improve therapeutic effects and stability of Garlen's compositions.

Claim Objections

11. Claims 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


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12. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

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January 8, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
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